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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/532,879	04/25/2006	Bent Karsten Jakobsen	006090.00017	9328

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EXAMINER	
WESSENDORF, TERESA D	
ART UNIT	**PAPER NUMBER**
1639	

MAIL DATE	DELIVERY MODE
07/12/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/532,879	JAKOBSEN ET AL.	
	Examiner	Art Unit	
	T. D. Wessendorf	1639	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final. for restriction only.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-85 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) 1-85 are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☒ Other: CRF

DETAILED ACTION

Election/Restrictions

Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claim(s) 1 and 3-6, drawn to a proteinaceous particle displaying on its surface a T-cell receptor wherein the proteinaceous particle are those recited from (i)-(iv).

Group II, claim(s) 2, drawn to a proteinaceous particle, displaying on its surface a dimer T-cell receptor.

Group III, claim(s) 1 and 7, drawn to a proteinaceous particle with disulfide bond linkage.

Group IV, claim(s) 1 and 8-9, drawn to a proteinaceous particle displaying on its surface scTCR with two segments.

Group V, claim(s) 1 and 10-17, drawn to a proteinaceous particle displaying on its surface a scTCR containing a disulfide bond.

Group VI, claim(s) 1 and 18, drawn to a proteinaceous particle displaying on its surface a dTCR polypeptide pair.

Group VII, claim(s) 1 and 19-20, drawn to a proteinaceous particle with the dTCR or sTCR have amino acid sequences corresponding to an extracellular constant and variable domain sequences.

Group VIII, claim(s) 1 and 21, drawn to a proteinaceous particle displaying on its surface polypeptide sequences corresponding to non-human extracellular and human variable domain sequences.

Group IX, claim(s) 1 and 22-25, drawn to a proteinaceous particle displaying on its surface dTCR or sTCR that corresponds to a native TCR Ig domain sequence.

Group X, claim(s) 1, 23-24 and 26 drawn to a proteinaceous particle with Thr-48 substitutions.

Group XI, claim(s) 1, 23-24 and 27, drawn to a proteinaceous particle with Thr-45 substitutions.

Group XII, claim(s) 1,23-24 and 28 drawn to a proteinaceous particle with Tyr10 substitutions.

Group XIII, claim(s) 1, 23-24 and 29, drawn to a proteinaceous particle with Tyr 45 and Asp-59 substitutions.

Group XIV, claim(s) 1, 23-24 and 30 drawn to a proteinaceous particle with Ser-15 and Glu-15 substitutions.

Group XV, claim(s) 1, 23 and 31, drawn to a proteinaceous particle with C-terminus truncation relative to the native sequences.

Group XVI, claim(s) 1. 23 and 32-33, drawn to a proteinaceous particle with non-cys residue substitution for Cys.

Group XVII, claim(s) 1 and 34, drawn to a proteinaceous particle with no unpaired Cys residues.

Group XVIII, claim(s) 1, 23 and 35, drawn to a proteinaceous particle with N-terminal residue truncation

Group XIX, claim(s) 1 and 36, drawn to proteinaceous particle with a filamentous phage particle displaying on its surface a dimeric TCR.

Group XX, claim(s) 1, 8 and 37-40, drawn to a diverse library of dTCR polypeptide pairs or scTCR polypeptides.

Group XXI, claim(s) 41-47 and 53-54, drawn to nucleic acid encoding a dTCR polypeptide and expression system.

Group XXII, claim(s)41, 43, 46 and 48 drawn to an expression system with the sequence as mutated ribosome binding site.

Group XXIII, claim(s) 41, 43, 46 and 49, drawn to an expression system that are missense suppressor stop codon.

Group XXIV, claim(s) 41, 43, 46 and 50, drawn to an expression system in which the sequence is mutated start codon.

Group XXV, claim(s) 41,43,46 and 51, drawn to an expression system with promoter sequence amenable modification.

Group XXVI, claim(s) 41, 43, 46 and 52, drawn to an expression system with a number of codons.

Group XXVII, claim(s) 55 and 56, drawn to a method for identifying TCR.

Group XXVIII, claim(s) 57-58, drawn to a method for detecting TCR ligand complexes.

Group XXIX, claim(s) 59, drawn to a method of identifying inhibitor or the interaction between TCR.

Group XXX, claim(s) 8, 60-63 and 65-67, drawn to TCR specific for a given ligand.

Group XXXI, claim(s) 8, 60 and 64, drawn to a dimer TCR.

Group XXXII, claim(s) 8, 60, 68-69 and 83, drawn to TCR specific for HLA-A2 peptide complex.

Group XXXIII, claim(s) 8, 60, 68 and 70 drawn to a TCR comprising one or more of the beta chain variable domain amino acids.

Group XXXIV, claim(s) 8, 60, 68, 71 drawn to a TCR with the variable domain amino acids as recited shown in SEQ.ID. 171

Group XXXV, claim(s) 8, 60, 68, 72 drawn to a TCR with 105D of Seq. ID. 171..

Group XXXVI, claim(s) 8,60, 68 and 73, drawn to a TCR with 99V and 100P of Seq. ID. 171.

Group XXXVII, claim(s) 8, 60, 68 and 74, drawn to a TCR with 104H and 105P.

Group XXXVIII, claim(s) 8, 60, 68 and 75, drawn to TCR specific for HLA-A2.

Group XXXIX, claim(s) 8, 60, 76, drawn to a nucleic acid encoding TCR of claim 60.

Group XXXX, claim(s) 8, 60, 77, drawn to a TCR associated with a therapeutic compound.

Group XXXXI, claim(s) 8, 60, 78, drawn to TCR associated with an imaging compound.

Group XXXXII, claim(s) 8, 60, 79, drawn to TCR associated with a cytotoxic compound.

Group XXXXIII, claim(s) 8, 60, 80, drawn to TCR specific for SEQ. ID 21 complex.

Group XXXXIV, claim(s) 8, 60, 81 drawn to TCR specific for Seq. ID.22.

Group XXXXV, claim(s) 8, 60, 82, drawn to a treatment method.

Group XXXXVI, claim(s) 8, 60, 75 and 84, drawn to cancer treatment method.

The inventions listed as Groups I-XXVI and XXX-XXXXIV do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons: each of these inventions are drawn to structurally different compounds. For example the inventions of Group I-XIX are drawn to compounds with different mutations at different positions of eh sequences. Group XX however is drawn to diverse library. These two compounds are structurally different since library contains collection of compounds different from the single compound in having a specific structure. Likewise the compounds of Groups XXI-XXVI drawn to nucleic acids and expression vectors containing numerous mutants differ in structure from the protein/peptide compounds or to a library of proteinaceous compounds. Thus, different processes to produce or

make these compounds are involved and each of these structurally different compounds has different effects.

The inventions listed as Groups XXVII-XXIX and XXXXV-XXXXVI do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons: each of these groups are drawn to different methods i.e., screening/identifying, treatment method and so forth. Thus, each of these methods requires different process steps/components in order to accomplish the process. Each of these methods have different mode of operations/actions and/or different effects and/or results.

The inventions listed as Groups (I-XXVI and XXX-XXXXIV) and Groups XXVII-XXIX and XXXXV-XXXXVI do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons: each of these Groups are drawn to statutorily different subject matter of compounds and methods. See further the reasons above.

This application contains claims directed to more than one species of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

The species are as follows:

For Groups I, II, VIII, IX, XVII, XX and **XXI**:

1). Single chain TCR

2. Dimer TCR

For Group I:

In addition to the above, applicants are to elect a single proteinaceus particle as recited in claim 1 (i)-(iv).

Each of these species differs in structure and possibly functions and/or mode of operation. A prior art reference anticipating one species would not render obvious the other species. For example, a ribosome particle differs in mode of operation/action from that of the phage particle. Each of these requires different components in order to perform their specific function(s).

For Group V:

A single species of the general formula P-A-A-P of a linker sequence.

Each of these species differs in structure and possibly functions and/or mode of operation. A prior art reference anticipating one species would not render obvious the other species.

For Group XXXII:

A single species of Seq. ID. 172, 173, 174 or 175.

Each of these species differs in structure and possibly functions and/or mode of operation. A prior art reference anticipating one species would not render obvious the other species.

Applicant is required, in reply to this action, to elect a single species to which the claims shall be restricted if no generic claim is finally held to be allowable. The reply must also identify the claims readable on the elected species, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

The claims are deemed to correspond to the species listed above in the following manner:

See above

The following claim(s) are generic: 1, 2, 10, 21, for example.

The species listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or corresponding special technical features for the following reasons: see above under the subgroups.

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the requirement be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention or species may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

Should applicant traverse on the ground that the inventions or species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions or species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C.103(a) of the other invention.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim

remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and the product claims are subsequently found allowable, withdrawn process claims that depend from or otherwise require all the limitations of the allowable product claim will be considered for rejoinder. All claims directed to a nonelected process invention must require all the limitations of an allowable product claim for that process invention to be rejoined.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103 and 112. Until all claims to the elected product are found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowable product claim will not be rejoined. See MPEP § 821.04(b). Additionally, in order to retain the right to rejoinder in accordance with the above policy, applicant is advised that the process claims should be amended during prosecution to require the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.** Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to T. D. Wessendorf whose telephone number is (571) 272-0812. The examiner can normally be reached on Flexitime.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Schultz can be reached on 571 272-0763. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

T. D. Wessendorf
Primary Examiner
Art Unit 1639

Tdw
July 9, 2007

UNITED STATES DEPARTMENT OF COMMERCE
U.S. Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
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APPLICATION NO./ CONTROL NO.	FILING DATE	FIRST NAMED INVENTOR / PATENT IN REEXAMINATION	ATTORNEY DOCKET NO.
10532879	4/25/2006	JAKOBSEN ET AL.	006090.00017

BANNER & WITCOFF, LTD.
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WASHINGTON, DC 20005-4051

EXAMINER
T. D.. Wessendorf

ART UNIT	PAPER
1639	1

DATE MAILED:

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner for Patents

This application contains sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 CFR 1.821(a)(1) and (a)(2). However, this application fails to comply with the requirements of 37 CFR 1.821 through 1.825 for the reason(s) set forth below or on the attached Notice To Comply With Requirements For Patent Applications Containing Nucleotide Sequence And/Or Amino Acid Sequence Disclosures. The Seq. ID. Nos. for the sequences recited in claims 16 and 17 are missing. Applicants are requested to check for other sequences in the specification or drawings to make sure that the sequences have Seq. ID. No.

Applicant is given ONE MONTH, or THIRTY DAYS, whichever is longer, from the mailing date of this letter within which to comply with the sequence rules, 37 CFR 1.821 - 1.825. Failure to comply with these requirements will result in ABANDONMENT of the application under 37 CFR 1.821(g). Extensions of time may be obtained by filing a petition accompanied by the extension fee under the provisions of 37 CFR 1.136(a). In no case may an applicant extend the period for reply beyond the SIX MONTH statutory period. Direct the reply to the undersigned. Applicant is requested to return a copy of the attached Notice to Comply with the reply.

T. D. Wessendorf
Primary Examiner
Art Unit: 1639
7/7/07

PTO-90C (Rev.04-03)

Application No: 10/532,879

NOTICE TO COMPLY WITH REQUIREMENTS FOR PATENT APPLICATIONS CONTAINING NUCLEOTIDE SEQUENCE AND/OR AMINO ACID SEQUENCE DISCLOSURES

Applicant must file the items indicated below within the time period set the Office action to which the Notice is attached to avoid abandonment under 35 U.S.C. § 133 (extensions of time may be obtained under the provisions of 37 CFR 1.136(a)).

The nucleotide and/or amino acid sequence disclosure contained in this application does not comply with the requirements for such a disclosure as set forth in 37 C.F.R. 1.821 - 1.825 for the following reason(s):

☒ 1. This application clearly fails to comply with the requirements of 37 C.F.R. 1.821-1.825. Applicant's attention is directed to the final rulemaking notice published at 55 FR 18230 (May 1, 1990), and 1114 OG 29 (May 15, 1990). If the effective filing date is on or after July 1, 1998, see the final rulemaking notice published at 63 FR 29620 (June 1, 1998) and 1211 OG 82 (June 23, 1998).

☐ . This application does not contain, as a separate part of the disclosure on paper copy, a "Sequence Listing" as required by 37 C.F.R. 1.821(c).

☐ 3. A copy of the "Sequence Listing" in computer readable form has not been submitted as required by 37 C.F.R. 1.821(e).

☐ . A copy of the "Sequence Listing" in computer readable form has been submitted. However, the content of the computer readable form does not comply with the requirements of 37 C.F.R. 1.822 and/or 1.823, as indicated on the attached copy of the marked -up "Raw Sequence Listing."

☐ 5. The computer readable form that has been filed with this application has been found to be damaged and/or unreadable as indicated on the attached CRF Diskette Problem Report. A Substitute computer readable form must be submitted as required by 37 C.F.R. 1.825(d).

☐ 6. The paper copy of the "Sequence Listing" is not the same as the computer readable from of the "Sequence Listing" as required by 37 C.F.R. 1.821(e).

☒ . Other: **specification (drawings or Brief Description thereof) must be revised to insert sequence identifiers to insure compliance.**

Applicant Must Provide:

☒ An initial or **substitute** computer readable form (CRF) copy of the "Sequence Listing".

☒ An initial or **substitute** paper copy of the "Sequence Listing", as well as an amendment directing its entry into the specification.

☒ A statement that the content of the paper and computer readable copies are the same and, where applicable, include no new matter, as required by 37 C.F.R. 1.821(e) or 1.821(f) or 1.821(g) or 1.825(b) or 1.825(d).

For questions regarding compliance to these requirements, please contact:

For Rules Interpretation, call (703) 308-4216
For CRF Submission Help, call (703) 308-4212
PatentIn Software Program Support
Technical Assistance.....703-287-0200
To Purchase PatentIn Software.....703-306-2600

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